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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,908	07/21/2003	Paul John Kawula	50623.245	5357
7590	11/29/2007			
Charles E. Runyan Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 11/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/623,908	KAWULA, PAUL JOHN
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 September 2007.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6-49 is/are pending in the application.
- 4a) Of the above claim(s) 9-21,24-26 and 30-46 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-8,22,23,27-29 and 47-49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

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## DETAILED ACTION

### ***Information Disclosure Statement***

Applicant requested clarification on the considered IDS and the Examiner would like to note that some references were cited twice and the Examiner crossed out the duplicate. Other references not in the English language were not considered since no explanation of the relevance was submitted.

### ***Specification***

The disclosure is objected to because of the following informalities: reference character "120" has been used (page 10, lines 15,18-20) to designate both *ceramic component* and *metallic surfaces*. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48,49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48,49 recite the limitation "the **stent**" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,22,23,27,47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serbousek et al. (5916269) in view of Shoher et al. (4434211) and Koch et al. (5181926). Serbousek et al. disclose (Fig. 1) a medical implant **10** with an outer surface **20** that engages a femoral head. Serbousek also discloses the device is made of metal, (col. 5, lines 41-46). Serbousek additionally discloses (Fig. 2) attachment regions with a plurality of bearing inserts **30**. However, Serbousek fails to disclose the inserts are ceramic having different porous regions. Koch et al. teach (Fig. 2) the surface of the implant has an indentation for an insert and is made of ceramic, col. 2, lines 53,54. Shoher et al. teaches that ceramics can be fused or bonded to metal surfaces and is important in the prosthetic art, col. 2, lines 7-9,27,28,47, col. 4, lines 40,41. Shoher also teaches that metal material is used to bond the ceramic to the metal substrate and can be silver, gold, platinum, etc. col. 3, lines 13,38-41. It would have been obvious to one of ordinary skill in the art to use ceramic inserts as taught by Koch et al. and modify the surface of the medical device of Serbousek et al. such that it provides a more wear resistant surface and use the bonding method of Shoher et al. to secure the ceramic component in the surface. It is well known in the art that ceramics provide a good wear surface and by using a ceramic eliminates the harmful wear particles that develop on metal to metal bearing surfaces. Regarding claims 48,49, the Examiner interprets the claims to just be an implant body.

Claims 7,8,28,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serbousek et al. '269 in view of Shoher et al. '211 and Koch et al. '926 in view of Alt (6099561). Serbousek et al. in view of Shoher et al. and Koch et al. is explained above. However, Serbousek et al. as modified by Shoher et al. and Koch et al. fail to disclose a drug for use in the implantable device. Alt discloses that drugs can be incorporated with ceramic coated implants, col. 10, lines 42-61. It would have been an obvious expedient to one of ordinary skill in the art to incorporate an anti-inflammatory drug in the porous ceramic as taught by Alt with the implantable device of Serbousek as modified by Koch and Shoher because of the body's defense mechanisms and thus the drug would aid in reducing inflammation at the implantation site.

Regarding claim 28, it would have been obvious to one of ordinary skill in the art to utilize the ceramic component with a metal substrate, such as taught by Alt since the ceramic provides a variety of capabilities for the user with one use being drug delivery. Further, Lambert (5900246) teaches that drug delivery devices include stents and joint implants, col. 3, lines 14,17,18 and claim 1. Thus, one of ordinary skill in the art would take the teachings of Serbousek in view of Koch and Shoher to use them in the stent art to form a stent with drug delivery capability per the teaching of Alt. Lambert suggests that the application of a drug to a medical device is the same field of endeavor for stents and joint implants.

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***Response to Arguments***

Applicant's arguments with respect to claims 6,27 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Brian Pellegrino*

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

TC 3700, AU 3738